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Abbott Laboratories
c/o Polsinelli Shughart PC
Two Prudential Plaza
180 N. Stetson Ave.
Suite 4525
Chicago, IL 60601

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,703,017

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,703,017, claims of which cover the human drug product LETAIRIS® (ambrisentan), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,025 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extensions for U.S. Patent Nos. 5,840,722, 5,932,730, and 7,109,205 based on the regulatory review period for LETAIRIS® (ambrisentan).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension in U.S. Patent Nos. 5,840,722, 5,932,730, and 7,109,205 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 5,703,017. In the absence of a request for reconsideration, and if U.S. Patent No. 5,703,017 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 1,025 days in U.S. Patent No. 5,703,017.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 10, 2009 (74 Fed. Reg. 6635). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,691 - 0) + 180

= 1,025 days (years)

Since the regulatory review period began May 3, 2002, after the patent issued (December 30, 1997), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,703,017
Granted:	December 30, 1997
Original Expiration Date[1]:	December 30, 2014
Applicant:	Ernst Baumann et al.
Owner of Record:	Abbott GmbH & Co. KG
Title:	3-(HET) Arylcarboxylic Acid Derivatives, Their Preparation And Intermediates for Their Preparation
Product Trade Name:	LETAIRIS® (ambrisentan)
Term Extended:	1,025 days
Expiration Date of Extension:	October 20, 2017

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7728

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: LETAIRIS® (ambrisentan)
Docket No.: FDA-2008-E-0113